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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/776,454	02/02/2001	Gregorio del Val	2001-0705	9327

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[REDACTED] EXAMINER

WHITEMAN, BRIAN A

[REDACTED] ART UNIT      [REDACTED] PAPER NUMBER

1635

DATE MAILED: 10/22/2002

14

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/776,454	VAL ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Brian Whiteman	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 24 April 2002.
- 2a) This action is **FINAL**.                  2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-8, 10, 12 and 22-41 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-8, 10, 12 and 22-41 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

- |   |  |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                          | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>11</u> . | 6) <input type="checkbox"/> Other: _____ .                                   |

**DETAILED ACTION**

**Non-Final Rejection**

Claims 1-8, 10, 12 and new claims 22-41 are pending examination.

Applicants' traversal, new abstract, the addition of new claims 22-42, the cancellation of claims 8, 11, 13-21, the amendment to claims 1, 2, 4, 6, 7, 10, and 12 in paper no. 13 is acknowledged and considered.

***Claim Objections***

The objection to the abstract is moot in view of the amended abstract.

The objection to claims 1, 4, 9 and 10 are moot in view of the amendment of the claims.

However, a new objection follows in view of the amendment to claim 1 and new claims 22, and 32.

Claims 1, 22, and 32 are objected to because of the following informalities: the phrase "modified to product **that** protein" on line 2. Suggest replacing "that" with "the". Appropriate correction is required.

The rejection under 112 paragraph (In re Mayhew) for claims 1 and 2 is moot in view of the amendment to the claims. However, in view of the amendment to claim 2 and the addition of claims 23 and 33 a new rejection under 11 first paragraph follows:

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2, 23-31, and 33 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for 1) A method for testing the allergenicity of a heterologous protein produced by a plant that had been genetically modified to produce the protein, comprising the following steps: (a) sensitizing a newborn dog from an atopic dog colony with a first extract prepared from tissue of the genetically modified plant and containing a mixture of plant proteins and the heterologous protein, by applying the first extract to the skin of the newborn dog, (b) after a period sufficient to allow the dog to establish an immune response to the extract, challenging the dog with the extract, (c) observing the degree of allergic response provoked, (d) if a detectable skin reaction is observed, comparing the degree of the allergic reaction observed with that observed by carrying out steps (a)-(c) above, but where the sensitizing step (a) or challenging step (b) is carried out with a second plant extract containing the same proteins as the first extract but lacking the heterologous protein, wherein the challenging (b) and observing (c) are carried out in the same manner for both the first and second extract, and (e) if the degree of allergic reaction at (c) is greater than that observed by carrying out steps (a)-(c) in accordance with step (d), identifying the heterologous protein as a potential allergen in humans; 2) The method of 1, wherein said challenging and observing steps consist of applying the first **and** second extract to a skin region of the dog and observing a local wheal reaction at the application site as the allergic response (skin test), and does not reasonably provide enablement for the full breadth of the claimed invention. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The claimed invention encompasses “A method for testing the allergenicity of a heterologous protein produced by a plant that had been genetically modified to produce the protein, comprising the following steps: (a) sensitizing a newborn dog from an atopic dog colony with a first extract prepared from tissue of the genetically modified plant, containing a mixture of plant proteins and the heterologous protein, by applying the extract to the skin of the newborn dog, (b) after a period sufficient to allow the dog to establish an immune response to the extract, challenging the dog with the extract, (c) observing the degree of allergic response provoked, (d) if a detectable skin reaction is observed, comparing the degree of skin reaction observed with that observed by carrying out steps (a)-(c) above, but where the sensitizing step (a) or applying step (b) is carried out with a control plant containing the same proteins as the first extract but lacking the heterologous protein, and (e) if the degree of skin reaction at (c) is greater than that observed by carrying out steps (a)-(c) in accordance with step (d), identifying the heterologous protein as a potential allergen in humans” (page 32).

It appears from the specification that the active step for determining a degree of allergic response of a heterologous protein isolated from a genetically modified plant is by comparing the allergic response from a specific test (e.g. skin test) to a control extract using the same test (e.g. skin test). More specifically, the as-filed specification teaches that each test requires a different step for observing the degree of allergic response (pages 13-15). The claimed invention contemplates using several different allergy tests at the same time. In view of the lack of guidance provided by the as-filed specification for comparing a reaction from a skin test to a reaction of a feeding test, it would take one skilled in the art an undue amount of experimentation to reasonably correlate using the same test with both extracts to using a one test (skin test) for the

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first extract and using a different test (feeding test) for the second extract. Therefore, the steps for observing and challenging using a specific allergy test and comparing it to any other allergy test other than the same allergy test are not enabled by the disclosure.

In conclusion, the as-filed specification and claims coupled with the state of the art at the time the invention was made only provide sufficient guidance and/or evidence to reasonably enable the for 1-2 listed above. Given that the examples in the specification only provide sufficient guidance for using the same test for both extracts, and given the lack of sufficient guidance to compare the reaction from a one test (skin test) to the reaction of a different test (feeding test) as cited in the claims, one skilled in the art would have to engage in a large quantity of experimentation in order to practice the claimed invention based on the applicant's disclosure and the different location of observing required for each different test.

Applicants' traversal is not found persuasive to the new rejection under 112 first paragraph because it is not applicable to the new rejection described above.

The rejection for claims 1, 2, 9 and 11 under 11 second paragraph are moot in view of the amendment to the claims. However, in view of the amendment to the claims and the addition of new claims, a new rejection under 112 second paragraph follows:

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 1-8, 10, 12, and 22-41 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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The term "the extract" in claims 3, 24, 34 is a relative term, which renders the claims indefinite. The term "the extract" is not defined by the claims, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The metes and bound of the term are not defined by the disclosure. More specifically, there are two extracts in the independent claim and it is not apparent which extract is being referred to. Suggest amending the term in each claim to read as follows: "the first and second extract" or "the first or second extract".

Applicants' traversal is not found persuasive to the new rejection under 112 second paragraph because it is not applicable to the new rejection under 112 second paragraph.

The term "substantially" in claims 1-8, 10, 12, 22-41 is a relative term, which renders the claims indefinite. The term "substantially" is not defined by the claims, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The metes and bound of the term are not defined by the disclosure. More specifically, the scope of the term is not understood when read in light of the specification. The specification does not point out and define "a second extract containing substantially the same protein as the first extract (e.g. claim 1)" or "substantially no allergic reaction is observed (e.g. claim 6)".

Suggest removing the term "substantially" from each claim.

Applicants' traversal is not found persuasive to the new rejection under 112 second paragraph because it is not applicable to the new rejection under 112 second paragraph.

No claims are allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kay Pinkney whose telephone number is (703) 305-3553.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Whiteman whose telephone number is (703) 305-0775. The examiner can normally be reached on Monday through Friday from 7:00 to 4:00 (Eastern Standard Time), with alternating Fridays off.

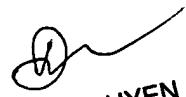
If attempts to reach the examiner by telephone are unsuccessful, the examiner's mentor, primary examiner, Dave Nguyen can be reached at (703) 305-2024.

If attempts to reach the primary examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader, SPE - Art Unit 1635, can be reached at (703) 308-0447.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Brian Whiteman  
Patent Examiner, Group 1635  
10/18/02

  
DAVET. NGUYEN  
PRIMARY EXAMINER